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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/503,606	07/18/95	SHORT	J 331400-21

18M2/0207
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EXAMINER

LAU, K

ART UNIT	PAPER NUMBER
1814	5

DATE MAILED: 02/07/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 (three) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-6 is/are pending in the application.

Of the above, claim(s) 2, 3, 5 and 6 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-6 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 4, drawn to enzyme kits as well as methods for producing them, classified in class 435, subclass 183.
 - II. Claims 2, 3, 5 and 6, drawn to methods of screening libraries for enzymes, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are patentably distinct from each other. The enzyme kits and methods to produce them of Group I and the methods to screen libraries of Group II do not require each other for their practice; have separate utilities, such as use of the Group I kits for their enzymatic activity versus use of the Group II methods to detect new enzymes; and are subject to separate manufacture and sale. The Groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.
3. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

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4. In a telephonic conversation with Charles J. Herron on October 10, 1996 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 4. Affirmation of this election must be made by Applicant in responding to this Office action. Claims 2, 3, 5 and 6 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to non-elected inventions.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Specification

6. The use of the trademarks lambda ZAP and Sephacryl (pg 12, lines 13, 26 and 27) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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7. The disclosure is objected to because of the following informalities: there is an undefined acronym "CTAB" on page 12, line 6.

Appropriate correction is required.

Drawings

8. This application has been filed with informal drawings declared as such by Applicant which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 U.S.C. § 112

9. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for enzyme kits comprising enzymes isolated by conventional means, does not reasonably provide enablement for kits comprising enzymes isolated by the disclosed screening methods. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claims, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The Examiner notes

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that inclusion of claim 1 in this rejection is based upon a reasonably broad interpretation of the claim as encompassing kits produced by the method of claim 4.

While the specification discloses methods for isolating enzymes by screening expression libraries for general and specific enzyme “chemical characteristics”, the sole example concerning the screening process (Example 2) stops with a putative designation at Tier 2 of “amide”. This level of disclosure provides insufficient guidance for one skilled in the art to proceed to identify enzyme chemical characteristics present in the enormous number of other enzymes. Enzyme activities are grouped into the six IUB classes based upon a determination of their specific activities rather than an initial determination of a generic activity such as “hydrolase” followed by increasing specificity of the actual activity. This is necessary the case because numerous enzymes are so specific that they will not act on a generic substrate that can lead to designation of a generic activity. Even in the case of Example 2, there is *a priori* no basis for the skilled artisan to expect that all, or even a significant number, of hydrolases would react with the first substrate (MuPheAFC) used. This unpredictability extends to the next tier where there is a similar lack of basis for the skilled artisan to expect “ester”, “amide”, or “acetal” enzymes to react with the three subsequent substrates used in Example 2. Assuming appropriate solutions through the above two tiers, the amount of experimentation necessary in the subsequent chemical tiers is enormous because of the tremendous number of possible specific substrates that may be necessary to hone in on the specific activity of any given enzyme. While recombinant and screening techniques are available, it is not routine in the art to screen large numbers of possible substrates where the expectation of detecting and obtaining

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enzymes with particular activities/functions is unpredictable based on the instant disclosure. Thus the skilled artisan would require guidance, such as appropriate generic substrates at each level of the chemical characterization, in order to make and use enzyme kits and screening methods in a manner commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by GibcoBRL.

GibcoBRL teach a kit for cDNA synthesis which comprises *E. coli* DNA ligase, polymerase I, and RNase H; T4 DNA ligase, DNA polymerase I, and polynucleotide kinase; and a reverse transcriptase. Since these enzymes have multiple chemical and physical characteristics in common (such as similar catalytic activities and optimal pH ranges), GibcoBRL anticipates the claims. The Examiner notes that recitation of "recombinant" imparts no novelty since that only refers to a method of making the products encompassed by the claims.

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11. Any inquiry concerning this communication or earlier communications should be directed to Kawai Lau whose telephone number is 703-308-4209. The examiner can normally be reached Monday-Friday from 7 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Wax, can be reached at 703-308-4216.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703-308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission to the attention of the examiner in Art Unit 1814. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (October 19, 1988) and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The FAX telephone number is 703-305-7401. Note: If applicants do submit a paper by facsimile, the original signed copy should be retained by applicants or applicants' representative. No duplicate copies should be submitted so as to avoid the processing of duplicate papers in the Office.

Kawai Lau, Ph.D.
February 3, 1997



ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180